

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 3, 2020

Bridget Peterson Regulatory Specialist II Ecolab Inc. 1 Ecolab Place St. Paul, MN 55102

Subject: PRIA Label Amendment – Adding new Public Health Use Sites

Product Name: Synergex

EPA Registration Number: 1677-250

Application Date: 10/16/2019 Decision Number: 556560

Dear Ms. Peterson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Inyderman

Enclosure: Stamped Label

### **Synergex**

# SANITIZER, DISINFECTANT, VIRUCIDE\*, FUNGICIDE DISINFECTANT

Acid Liquid Sanitizer for Food Processing Equipment in Dairies, Dairy Farms, Breweries, Wineries, Beverage, Food Processing Plants, Grain Mills, Oilfields and Bio-Refining Processes

Disinfectant for Farms, Livestock Quarters, Poultry Premises, Poultry Hatcheries, and Industrial Facilities

Sanitizer and Disinfectant for the Pharmaceutical and Personal Care Industry

#### **Active Ingredients:**

Hydrogen Peroxide	10.70%
Peroxyoctanoic Acid	0.63%
Peroxyacetic Acid	
Other Ingredients:	
Total:	

### ACCEPTED

03/03/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1677-250

# KEEP OUT OF REACH OF CHILDREN MANTÉNGASE FUERO DEL ALCANCE DE LOS NIÑOS

### DANGER | PELIGRO

(Note to reviewer: First aid statements must be located on the front panel to be consistent with 40 CFR) (See [front] [top] [label] [panel] for [precautionary statements] [and] [first aid]

(See [back], [side], [inner] [inside] [other] [fold-out] [booklet] [hang tag] [product container] [label(s)] [panel(s)] [container] for [complete] [additional] [information] [directions for use] [precautionary statements] [and] [storage and disposal] [container handling and disposal])

(Please [refer to] [see] reference sheet for [additional] [directions for use] [information])

#### PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER:** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. After the product has been diluted according to use directions Personal Protective equipment is not required.

#### **FIRST AID**

**IF IN EYES**: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING**: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 –20 minutes. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED**: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or going for treatment.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026 OUTSIDE NORTH AMERICA, CALL +1-651-222-5352

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

**PHYSICAL AND CHEMICAL HAZARDS**: Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

**ENVIRONMENTAL HAZARDS** (containers greater than 5 gallons): This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### **SANITIZATION**

Synergex acid sanitizer is recommended for use on pre-cleaned, hard, non-porous surfaces in food and beverage processing, industrial, and institutional applications. [This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO<sub>3</sub>.]

**NOTE:** FOR MECHANICAL OPERATIONS prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS fresh sanitizing solutions must be prepared at least daily or more often if the solution becomes diluted or soiled.

#### **Sanitizing Food Contact Surfaces**

Prior to sanitizing, remove gross food particles, and then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1 fl. oz. Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm–1950 ppm product or 1.12–1.95 ml/L). At this dilution Synergex is effective as a food contact surface sanitizer against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229), as well as food pathogens *Escherichia coli* O157:H7 (ATCC 35150), *Escherichia coli* O26:H11 (STEC), *Escherichia coli* O45:H2 (STEC), *Escherichia coli* O103:H6 (STEC), *Escherichia coli* O111:H8 (STEC), *Escherichia coli* O121:H19 (STEC), *Escherichia coli* O145:NM (STEC), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (ATCC 13311), *Campylobacter jejuni* (ATCC 29428), *Cronobacter sakazakii* (ATCC 12868), *Pseudomonas aeruginosa* (ATCC 15442) and *Vibrio cholerae* (ATCC 25873). At the same dilution Synergex is effective at reducing spoilage causing organisms *Pediococcus damnosus* (ATCC 25248) and *Lactobacillus malefermentans* (ATCC 11305). Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces must be exposed to the sanitizing solution for a period of 1 minute unless a longer time is specified by the governing sanitary code. Drain thoroughly. [Do not rinse.] [No rinse necessary.]

#### **Continuous Treatment of Conveyors**

Wash, rinse and sanitize conveyor equipment. During processing, apply Synergex at a concentration of 1 fl. oz. Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112-0.195% v/v or 1120 ppm-1950 ppm product or 1.12-1.95 ml/L) to conveyor with Mikro Master or other suitable feeding equipment. At this dilution Synergex is effective against Staphylococcus aureus (ATCC 6538) and Escherichia coli (ATCC 11229), as well as food pathogens Escherichia coli O157:H7 (ATCC 35150), Escherichia coli O26:H11 (STEC), Escherichia coli O45:H2 (STEC), Escherichia coli O103:H6 (STEC), Escherichia coli O111:H8 (STEC), Escherichia coli O121:H19 (STEC), Escherichia coli O145:NM (STEC), Listeria monocytogenes (ATCC 49594), Salmonella typhimurium (ATCC 13311), Campylobacter jejuni (ATCC 29428), Cronobacter sakazakii (ATCC 12868), and Vibrio cholerae (ATCC 25873) as well as reducing spoilage organisms Pediococcus damnosus (ATCC 25248) and Lactobacillus malefermentans (ATCC 11305). Controlled volumes of Synergex are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of Synergex from equipment and to prevent puddles on top of belt. During interruptions in operations, coarse spray the processing equipment with Synergex solution at 0.112–0.195% v/v concentration. Conveyor equipment must be free of food product when applying coarse spray. Conveyor surface must be exposed to the sanitizing solution for a period of 1 minute.

#### Final Bottle [and Closure] Sanitizing Rinse

Synergex may be used as a final sanitizing rinse for returnable and non-returnable bottles (e.g. glass or PET) (and/or closures) at dilution rate of 1 fl. oz. Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm–1950 ppm product or 1.12–1.95 ml/L). At this dilution Synergex is effective as a food contact surface sanitizer against Staphylococcus aureus (ATCC 6538) and Escherichia coli (ATCC 11229), as well as food pathogens Escherichia coli O157:H7 (ATCC 35150), Escherichia coli O26:H11 (STEC), Escherichia coli O45:H2 (STEC), Escherichia coli O103:H6 (STEC), Escherichia coli O111:H8 (STEC), Escherichia coli O121:H19 (STEC), Escherichia coli O145:NM (STEC), Listeria monocytogenes (ATCC 49594), Salmonella typhimurium (ATCC 13311), Campylobacter jejuni (ATCC 29428), Cronobacter sakazakii (ATCC 12868), and Vibrio cholerae (ATCC 25873) as well as reducing spoilage organisms Pedicoccus damnosus (ATCC 25248) and Lactobacillus malefermentans (ATCC 11305). All surfaces must be exposed to the sanitizing solution for a period of 1 minute. Drain thoroughly. [Do not rinse.] [No rinse necessary.] (Suitable for use in bottle rinse applications.)

### **Antimicrobial Rinse for Pre-Cleaned Food Contact Surfaces**

Prior to antimicrobial rinsing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. To reduce the number of spoilage organisms *Bacillus coagulans* (ATCC 7050) and *Clostridium butyricum* (ATCC 19398), apply Synergex at a concentration of 1 fl. oz. per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm–1950 ppm product or 1.12–1.95 ml/L) at a temperature of 50°C to 60°C for at least 5 minutes. Drain thoroughly. [Do not rinse.] [No rinse necessary.]

## Antimicrobial Rinse of Pre-Cleaned or New Returnable or Non-Returnable Containers [and Closures]

To reduce the number of beverage spoilage organisms *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305), *Saccharomyces cerevisiae* (ATCC 834) and *Penicillium digitatum* (ATCC 36038), apply Synergex at a concentration of 0.64–2.56 fl. oz. per gallon of [water] [tap water] [up to 500 ppm hard water] (0.5–2% v/v or 5000 ppm–20,000 ppm product or 5–20 ml/L) at a temperature of 40°C to 60°C for a minimum contact time of 7 seconds. After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305) and *Saccharomyces cerevisiae* (ATCC 834), apply Synergex at a concentration of 0.64–2.56 fl. oz. per gallon of [water] [tap water] [up to 500 ppm hard

water] (0.5–2% v/v or 5000 ppm–20,000 ppm product or 5–20 ml/L) at a temperature of 15°C to 60°C for a minimum contact time of 15 seconds. After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

#### **Antimicrobial Rinse for Yeast Reduction**

Remove gross food particles, and then wash with a detergent solution, followed by a potable water rinse. To reduce the number of food spoilage organisms *Saccharomyces cerevisiae* (ATCC 834) apply 1 fl. oz. of Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm–1950 ppm product or 1.12–1.95 ml/L) for at least 1 minute. Drain thoroughly. [Do not rinse.] [No rinse necessary.]

#### Sanitizing Hard, Non-Porous, Non-Food Contact Surfaces

Prior to use of this product, remove gross soil particles from surfaces. Wash with a detergent solution and rinse with potable water. Sanitize hard, non-porous, non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, and drip pans with 1 fl. oz. of Synergex concentrate per 4–8 gallons of [water] [tap water] [up to 500 ppm hard water] (0.098–0.195% v/v or 980 ppm–1950 ppm product or 0.98–1.95 ml/L). Apply use solution using a cloth, mop, sponge, coarse sprayer, or by immersion. At this concentration the product is effective as a non-food contact surface sanitizer against the following organisms: *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (ATCC 13311), *Pseudomonas aeruginosa* (ATCC 15442), *Cronobacter sakazakii* (ATCC 12868), *Escherichia coli* O157:H7 (ATCC 35150) and *Campylobacter jejuni* (ATCC 29428) as well as reducing spoilage organisms *Lactobacillus malefermentans* (ATCC 11305). All surfaces must be exposed to the sanitizing solution for a period of 5 minutes. Drain thoroughly. [Do not rinse.] [No rinse necessary.]

## Sanitizing Hard, Non-Porous, Non-Edible Outside Surfaces of Airtight, Sealed Packages Containing Food or Non-Food Products

Synergex may be used as a final sanitizing rinse for hard, non-porous, non-edible outside surfaces of airtight, sealed packages containing food or non-food products at 1 fl. oz. of Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120ppm–1950ppm product or 1.12–1.95ml/L). The treated hard, non-porous, non-edible packaging, such as food wraps and meat casings, must be removed and discarded before packaged food products are further processed or consumed. All surfaces must be exposed to the sanitizing solution for a period of 1 minute. Drain thoroughly. No rinse necessary. This is not to be used on porous surfaces.

Foam Sanitizing Non-Food Contact Surfaces (This use not approved in the state of California) Synergex in conjunction with Liquid K is an effective foam sanitizer of pre-cleaned, non-food contact surfaces such as floors, walls, drains, and equipment surfaces. For this application, prepare a solution of 1 fl. oz. of Synergex concentrate per 4–8 gallons of water (0.098–0.1950% v/v or 980ppm – 1950 ppm product or 0.98–1.95ml/L) and 1–2 fl. oz. Liquid K per 6 gallons [water] [tap water] [up to 500 ppm hard water] (0.13% – 0.26% v/v). For example, in 6 gallons of water, add 1 fl. oz. of Synergex and 1–2 fl. oz. of Liquid K. Liquid K is the only approved foam generator. At this concentration, the product is effective as a non-food contact surface sanitizer against the following organisms: Staphylococcus aureus (ATCC 6538), Enterobacter aerogenes (ATCC 13048), Listeria monocytogenes (ATCC 49594), Salmonella typhimurium (ATCC 13311), Escherichia coli O157:H7 (ATCC 35150) as well as reducing spoilage causing organisms Lactobacillus malefermentans (ATCC 11305). Apply solution as a foam using recommended equipment. Wet surfaces thoroughly with foam. Surfaces must be exposed to the sanitizing foam for a period of 5 minutes. Drain thoroughly. No rinse is necessary. Contact your Ecolab representative for information on Liquid K foaming agents and recommended foaming equipment.

#### **Sanitizing Non-Food Contact Packaging Equipment**

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution and rinse thoroughly with potable water. Sanitize non-food contact packaging

equipment with 1 fl. oz. of Synergex concentrate per 4–8 gallons of [water] [tap water] [up to 500 ppm hard water] (0.098–0.195% v/v or 980ppm – 1950 ppm product or 0.98–1.95ml/L). Apply use solution using a cloth, sponge, coarse sprayer, or by immersion. At this concentration the product is effective as a non-food contact surface sanitizer against the following organisms: *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (ATCC 13311), *Pseudomonas aeruginosa* (ATCC 15442), *Cronobacter sakazakii* (ATCC 12868), *Escherichia coli* O157:H7 (ATCC 35150) and *Campylobacter jejuni* (ATCC 29428) as well as reducing spoilage causing organisms (beverage spoilage organisms) *Lactobacillus malefermentans* (ATCC 11305). All surfaces must be exposed to the sanitizing solution for a period of 5 minutes. Allow surfaces to drain thoroughly before operations are resumed. Drainage may be followed by a potable or sterile water rinse.

#### **Sanitizing Biofilm**

Synergex acid sanitizer is recommended for use on pre-cleaned, hard, non-porous surfaces in food and beverage processing, industrial, and institutional applications.

When applied to pre-cleaned hard, non-porous food contact and other pre-cleaned, hard, non-porous surfaces conducive to biofilm formation, Synergex is effective as a biofilm sanitizer against *Listeria monocytogenes* (ATCC 49594) and *Pseudomonas aeruginosa* (ATCC 15442). Use a cleaning solution suitable to remove gross particles, followed by a potable water rinse as required by the governing sanitary code. Sanitize according to the table below using immersion, coarse spray or CIP circulation techniques as appropriate to the equipment. All surfaces must be exposed to the sanitizing solution for the required contact time unless a longer time is specified by the governing sanitary code. Drain thoroughly. See table for rinsing requirements.

Biofilm Sanitizing Treatment		
Use Rate	Minimum Conditions for Use	Post-Treatment Rinse Requirement
1 fl. oz. / 4–4.5 gallons of [water] [tap water] [up to 500 ppm hard water] (0.173–0.195%, 1730–1950 ppm product)	10 minutes (at a minimum of 33°C)	No rinse necessary
1 fl. oz. / 4–4.5 gallons of [water] [tap water] [up to 500 ppm hard water] (0.173–0.195%, 1730–1950 ppm product)	25 minutes (by immersion or CIP circulation)	No rinse necessary
1.54–1.92 fl. oz. / 3 gallons of [water] [tap water] [up to 500 ppm hard water] (0.40–0.50%, 4000–5000 ppm product)	5 minutes	Potable water rinse required

#### **Sanitizing Non-Porous Gloved Hands**

To prevent cross contamination of organisms between treated surfaces [in [animal areas] or [packaging and storage areas of] food plants], dip pre-washed (plastic, latex or other synthetic rubber) gloved hands into a suitable clean container that contains enough freshly made sanitizing solution to cover the gloved area. Do not let sanitizing solution come into contact with the exposed skin. Make up the sanitizing solution by adding 1 fl. oz. of Synergex concentrate per 4–8 gallons of [water] [tap water] [up to 500 ppm hard water] (0.098–0.195% v/v or 980 ppm – 1950 ppm product or 0.98–1.95ml/L). Dip (soak) in solution for 1 minute. NO POTABLE WATER RINSE IS ALLOWED. Change the sanitizing solution in the bath at least daily or when solution appears dirty.

**Entryway Sanitizing Systems** (This use is not approved in the state of California) To prevent cross contamination of organisms between treated surfaces, set the system to deliver sanitizing solution at 1 fl. oz. of Synergex concentrate per 4–8 gallons of [water] [tap water] [up to 500 ppm hard water] (0.098–0.195% v/v or 980 ppm – 1950 ppm product) and 1–2 fl. oz. Liquid K per 6 gallons of water (0.13% – 0.26% v/v). For example, in six gallons of water, add 1 fl. oz. of

Synergex and 1–2 fl. oz. of Liquid K. Liquid K is the only approved foam generator. The foam (or spray) must cover the entire path of the doorway. Set the system so that a wet blanket of sanitizer solution is maintained on the floor. Treated surfaces must remain wet for 1 minute. Do not mix other foam additives to the sanitizing solution.

**Shoe Bath Sanitizer Directions** (This use is not approved in the state of California) To prevent cross contamination of organisms between treated surfaces [in animal areas], shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Sanitize boots (shoes) in a solution of 1 fl. oz. of Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm – 1950 ppm product or 1.12–1.95 ml/L). Scrape gross soils from waterproof work boots (shoes) and place in solution for 1 minute prior to entering area. Change the solution in the bath daily or sooner if solution appears soiled.

Shoe Foam Sanitizer Directions (This use is not approved in the state of California) Synergex can be used to prevent cross contamination of organisms between treated surfaces [in [animal areas] and [packaging and storage areas of] food plants]. Apply a foam layer approximately 0.5–2 inches (1.3–5 cm) thick made from a solution of 1 fl. oz. of Synergex concentrate per 4–7 gallons of water (0.112–0.195% v/v or 1120 ppm – 1950 ppm product or 1.12–1.95 ml/L) and 1 fl. oz. Liquid K per 6 gallons of [water] [tap water] [up to 500 ppm hard water] (0.13% v/v). For example, in 6 gallons of water, add 1 fl. oz. of Synergex and 1–2 fl. oz. of Liquid K at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator/aerator. Scrape waterproof shoes. Stand and/or walk through foamed area for 1 minute prior to entering area. Foam area must be washed and replaced daily or when it appears soiled.

#### **Bacteriophage Control**

When applied to pre-cleaned surfaces, Synergex will reduce the incidence of bacteriophage *Lactococcus lactis* (DSM 4366: P001 DSM 4262 and P008 DSM 10567) in manufacturing establishments by spraying or immersion of equipment in a solution of 1 fl. oz. of Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm – 1950 ppm product or 1.12–1.95 ml/L). All surfaces must be exposed to the solution for a period of 1 minute. Drain thoroughly. [Do not rinse.] [No rinse necessary.]

#### **DISINFECTION**

Synergex disinfects as it cleans in one operation when used according to disinfection directions. Synergex can be used to disinfect floors, walls and other hard, non-porous, surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of use: Use Synergex in veterinary clinics, animal life science laboratories, industrial facilities, office buildings, recreational facilities, retail and wholesale establishments.

#### **Combination Disinfection and Cleaning**

Synergex is effective as a disinfectant at a concentration of 1–7.68 fl. oz. Synergex concentrate per 3 gallons (0.26–2% v/v concentration or 2600-20,000 ppm product or 2.6–20ml/L) of [water] [tap water] [up to 500 ppm hard water] and 5% blood serum on hard, non-porous surfaces. At this dilution, Synergex is effective against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708) and *Pseudomonas aeruginosa* (ATCC 15442).

For visibly soiled areas a pre-cleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. All surfaces must remain visibly wet for 10 minutes, and then remove solution and entrapped soil with a

clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted. Rinse food contact surfaces with a potable water rinse prior to reuse.

#### Disinfecting Hard, Non-Porous and Non-Food Contact Surfaces

Synergex is recommended for use on hard, non-porous environmental surfaces such as floors, walls and processing equipment. Synergex is effective against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708) and *Pseudomonas aeruginosa* (ATCC 15442) at a concentration of 1–7.68 fl. oz. Synergex concentrate per 3 gallons (0.26–2% v/v concentration or 2600 ppm – 20,000 ppm product or 2.6–20ml/L) of [water] [tap water] [up to 500 ppm hard water] and 5% blood serum. For visibly soiled areas a pre-cleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a visibly wet contact time of at least 10 minutes. Product contact surfaces must be rinsed with [potable] [sterile] water.

#### Virucidal\*

At 1 fl. oz. of Synergex concentrate per 4–7 gallons of [water] [tap water] [up to 500 ppm hard water] (0.112–0.195% v/v or 1120 ppm – 1950 ppm product or 1.12–1.95ml/L) Synergex is effective against \*Influenza B Virus (ATCC VR-823), \*Influenza A virus (H1N1) (Strain A/Mexico/4108/2009), and \*Reovirus Type 3 (ATCC VR-232) on hard, non-porous, inanimate surfaces when used at a 5 minute contact time in the presence of 5% blood serum. Apply as directed under disinfection.

#### **Fungicidal**

Synergex can be used on hard, non-porous, inanimate surfaces such as shower room floors, locker room benches, shower stalls and bath mats. At 1 fl. oz. of Synergex concentrate per 4–5.5 gallons of [water] [tap water] [up to 500 ppm hard water] (0.142–0.195% v/v or 1420 ppm – 1950 ppm product or 1.42–1.95ml/L) Synergex is effective against *Trichophyton interdigitale* (formerly known as *Trichophyton mentagrophytes*) (Athletes Foot Fungi) (ATCC 9533) in the presence of protein (5% blood serum) with a 10 minute contact time. Apply as directed under disinfection.

#### **Poultry and Swine Premise Disinfection**

- 1. Remove all poultry and feeds from premises, vehicles, and enclosures such as coops and crates.
- 2. Remove all litter and droppings from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- 3. Empty all troughs, racks and other feeding and watering appliances.
- 4. Thoroughly clean all surfaces with a suitable detergent and rinse with water.
- 5. Saturate surfaces with the recommended disinfecting solution for a period of at least 10 minutes.
- 6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure.
- 7. Ventilate buildings, vehicles, coops and other closed spaces. Do not house poultry and animals or employ equipment until treatment has been absorbed, set or dried.
- 8. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse.

See your Ecolab Representative for specific recommendations for all cleaning and rinsing requirements.

#### **Poultry Hatchery Disinfection**

Use to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces.

- 1. Remove all poultry, eggs, chicks and feeds from premises, vehicles, and enclosures such as coops and crates.
- 2. Remove gross soils, such as litter, down, shell fragments or other hatching related debris.
- 3. Empty all racks and other equipment and appliances.

- 4. Thoroughly clean all surfaces with a suitable detergent and rinse with water.
- 5. Saturate surfaces with the recommended disinfecting solution for a period of at least 10 minutes.
- 6. Immerse all trays, racks, carts and other types of equipment used in handling animals.
- 7. Ventilate buildings, vehicles and other closed spaces. Do not house poultry and animals or employ equipment until treatment has been absorbed, set or dried.
- 8. Thoroughly scrub treated hatchers, setters, trays, racks, carts with a detergent and rinse with potable water before reuse.
- 9. Allow to dry before reintroducing poultry, eggs, chicks and feeds.

#### **Farm Premise Disinfection**

- 1. Remove all animals and feed from premises, vehicles, and enclosures.
- 2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals.
- 3. Empty all troughs, racks and other feeding and watering appliances.
- 4. Thoroughly clean surfaces with soap or detergent by manual or spray application and rinse with water
- 5. Saturate surfaces with the recommended disinfecting solution for a period of at least 10 minutes.
- 6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.
- 7. Ventilate buildings, vehicles and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
- 8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

#### **Hard Surface Cleaner**

For hard surface cleaning applications, remove gross soil particles from surfaces. Then thoroughly clean surfaces with a concentration of 1–7.68 fl. oz. Synergex concentrate per 3 gallons of [water] [tap water] [up to 500 ppm hard water] (0.26–2% v/v or 2600 ppm – 20,000 ppm product or 2.6–20ml/L) in conjunction with an alkaline pH modifier, such as KOH or NaOH to adjust the cleaning solution to a pH of 8.8. All hard, non-porous, food contact surfaces treated with this cleaning system must be rinsed thoroughly with potable water followed by sanitizing with an approved food contact sanitizer.

For hard surface acid cleaning applications, remove gross food particles with a water rinse, then wash using Synergex at a rate of up to 1 fl. oz. per 4 gallons of [water] [tap water] [up to 500 ppm hard water] (0.195% v/v or 1950 ppm product or 1.95ml/L). All hard, non-porous, food contact surfaces treated with this cleaning system must be drained thoroughly. [No rinse necessary].

#### **Final Bottle and Closure Cleaning Rinse**

Synergex may be used as a final cleaning rinse for returnable and non-returnable bottles (e.g., glass or PET) and closures not requiring a final food contact surface sanitizing rinse when used at a rate of up to 1 fl. oz. per 4 gallons of [water] [tap water] [up to 500 ppm hard water] (0.195% v/v or 1950 ppm product or 1.95ml/L). Drain thoroughly. No rinse necessary.

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product must be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

#### CONTAINER HANDLING AND DISPOSAL:

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers >5-55 gallons.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(Totes) Verify that the container is empty. Do not rinse or clean. Seal and contact Ecolab for return.

## FOR INDUSTRIAL USE STRONG OXIDIZING AGENT

EPA Reg. No.: 1677-250

EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2(R), 1677-TX-1(D), 1677-OH-1(H), 1677-IL-2(J), 1677-GA-1(M),

1677-PR-1(B), 1677-CA-1(S), 1677-WV-1(V) Superscript refers to first letter of date code

Ecolab Inc. 1 Ecolab Place St. Paul, MN 55102

[Made in USA] [Made in United States of America]

This product may be patented | Ce produit peut être breveté | Este producto puede ser patentado: www.ecolab.com/patents

Net Contents: 1 U.S. Gallon (3.78 L) 2.5 U.S. Gallons (9.45 L)

> 4 U.S. Gallons (15.1 L) 15 U.S. Gallons (56.8 L) 30 U.S. Gallons (113.5 L) 50 U.S. Gallons (189 L) 300 U.S. Gallons (1135 L)(Tote) 304 U.S. Gallons (1150 L)(Tote)

#### **Optional Marketing Language:**

#### **Product Description:**

[3DT] SYNERGEX is a mixed peracid-based antimicrobial agent for use in a number of sanitizing and disinfecting applications as indicated in the Directions for Use.

[3DT] SYNERGEX can be monitored real-time, decreasing dependence on manual titrations. See separate instructions for using monitoring equipment.

#### **Promotes Quality Assurance**

- Allows for automatic monitoring of the entire CIP process.
- Improves continuous control of sanitizer concentrations.
- Improves concentration control in ESL and antimicrobial bottle rinse applications.
- Chemical concentration can be monitored real-time decreasing dependence on manual titrations. See separate instructions for using monitoring equipment.
- Effective against environmental microorganisms that can adversely affect product quality. See directions for use for list of organisms.
- Low foaming formulation minimizes CIP cycle time and improves efficiency.
- Leaves equipment surfaces shining sheeting action provides spotless, film-free equipment.
- Fast breaking foam lets you know that the sanitizer is present and doing its job in environmental sanitization applications.
- Effective against many microorganisms, listed in Directions for Use, at a variety of temperatures, helping reduce energy costs when used at lower temperatures. Other sanitizers are generally used at temperatures of 75°F or higher.
- [3DT] SYNERGEX concentration can be monitored real-time using fluorescence or conductivity, decreasing dependence on manual titrations.
- Registered for continuous treatment of conveyors in food processing operations.
- Reduces harmful microorganisms\* on critical meat, poultry and fruit/vegetable conveyor surfaces during processing.
- Effective against spoilage microorganisms\* that can adversely affect product quality.

#### **Delivers Antimicrobial Activity in a Variety of Applications and Conditions**

- [3DT] SYNERGEX is a mixed peracid acid sanitizer, enabling use at lower concentrations than peracetic acid alone, and provides antimicrobial activity against the organisms listed in Directions for Use.
- Useful for CIP, spray, soak or foam additive sanitizing applications with an approved additive such as Liquid K™. (Liquid K foam is not to be used in the state of California.)
- Suitable for use in bottle rinse applications.
- Registered for continuous treatment of conveyors in food processing operations, reducing microorganisms listed in the Directions for Use on critical meat, poultry and fruit/vegetable conveyor surfaces during processing.
- Formulated for rapid soil penetration and ability to stand up to organic loads.
- Suitable for use in bottle rinse applications.

#### **Helps Protect Processing Equipment Investment**

- Use solutions non-corrosive to 304, 316, and 410 stainless steel surfaces when used at recommended concentrations.
- Compatible with most plastic and rubber materials used in processing operations.

#### **Saves Time and Money**

Convenient to use - provides acidified rinse and sanitizer in one step - no post-rinse required.

<sup>\*</sup>For a list of organisms, see directions for use on product label.

• Useful for CIP, spray, and soak sanitizing applications, and can be used in foam sanitizing applications with approved additive, Liquid K. (Liquid K foam is not to be used in the state of California.)

- Eliminates the need for multiple sanitizers.
- Performs acid rinse and sanitizing in one step.
- Reduced employee exposure to concentrated product in drum packaged product, through the unique drum packaging closure.
- Leaves stainless steel surfaces free from mineral deposits low pH use solution aids in mineral, hard-water and milk soil removal.
- Leaves stainless steel surfaces shiny.
- Effective in the removal and elimination of pungent food additives, colorings, and flavorings from food processing and filling equipment.
- Improved productivity as improved mineral solubility helps reduce frequency of acid washes and labor needs.

#### **Environmental and Safety Implications**

- Enables reduced water consumption for CIP programs with a rinse post-sanitizer.
- Active ingredients rapidly break down after use into water, oxygen, acetic acid, and octanoic acid
- Improved mineral solubility helps reduce frequency of acid washes and chemistry usage.
- Reduced effluents due to lower use of concentration requirement.
- [Reduced] total volatiles and oxidizer in the air compared to peroxyacetic acid and traditional mixed peracid sanitizers.
- Improved Employee Safety because of dispenser engineering controls.

#### **Biofilm Sanitizing [Promotes Quality Assurance] [and Food Safety]**

- [Proven] [Developed] [Approved] [Formulated] to [kill] [reduce] [penetrate] [destroy] biofilms at sanitizer concentration
- Achieve a minimum 6-log reduction of biofilm bacteria at no rinse level
- Reducing your microbial load contained within biofilms by [6 logs] [99.9999%]
- Biofilm [penetrating] sanitizer for use on hard, non-porous food contact surfaces
- Sanitizer with food contact, no rinse claims for biofilms.
- Kill biofilms on hard, non-porous food contact surfaces.
- [Kill] [Reduce] biofilms on hard, non-porous food contact surfaces; [no rinse required]
- [Penetrates] [and] [kills] [and] [reduces] biofilms from hard, non-porous food contact surfaces
- For use on hard, non-porous surfaces
- Effective at [reducing] [and] [killing] biofilms on gaskets
- No rinse required on food contact surfaces
- Synergex has been developed to kill [at least] [a minimum of] [99.9999%] [6 logs] of pathogens in biofilms at non-rinse levels.
- Synergex [, when used as a no-rinse sanitizer,] can [penetrate] [and] [reduce] biofilms
- Synergex can improve your food safety program by reducing [at least] [a minimum of] 99.9999% [6 log] of biofilms as a no rinse sanitizer
- Synergex now has biofilm sanitizer claims. These claims allow a reduction of biofilms by [at least] [a minimum of] 99.9999% [6 log reduction]
- No rinse needed! Synergex now has biofilm claims at sanitizer levels.
- Synergex is effective at killing *Pseudomonas aeruginosa* and *Listeria monocytogenes* containing biofilms at [no rinse] sanitizer levels
- Synergex can destroy biofilms as a non-rinse sanitizer.
- Kill biofilms while sanitizing
- Synergex just got better. It now has no rinse, hard, non-porous surface biofilm claims. This means you are [killing] [penetrating] biofilms while you sanitize.
- Synergex controls biofilms

• Kills [a minimum of] [99.9999%] [6 log] of bacteria [Pseudomonas aeruginosa] [and] [Listeria monocytogenes] in biofilms on a hard, non-porous surfaces

- Kills a minimum of 99.9999% [6 log] of bacteria [*Pseudomonas aeruginosa*] [and] [*Listeria monocytogenes*] in biofilms as a no rinse sanitizer
- Reduces [at least] [a minimum of] 99.9999% [6 log] of bacteria [Pseudomonas aeruginosa] [and] [Listeria monocytogenes] growing in biofilms
- Formulated to kill 99.9999% [6 log] of bacteria [*Pseudomonas aeruginosa*] [and] [*Listeria monocytogenes*] in biofilms
- Reducing biofilms on hard, non-porous food contact equipment just got easier. Synergex now has food contact, no rinse biofilm claims.
- Kills biofilm [producing] [forming] bacteria [Pseudomonas aeruginosa] [and] [Listeria monocytogenes]
- Penetrates biofilms, killing [a minimum of 99.9999%] [6 log] of the bacteria [*Pseudomonas aeruginosa*] [and] [*Listeria monocytogenes*] [living there]
- Bacteria tested as a biofilm include Pseudomonas aeruginosa and Listeria monocytogenes
- Synergex is effective as a biofilm sanitizer against [Pseudomonas aeruginosa] and [Listeria monocytogenes]
- Increases shelf-life of food or beverage being manufactured as part of a comprehensive cleaning and sanitizing program
- Reduces spoilage causing organisms in biofilms that impact product shelf life
- Reduces pathogens contained in biofilms
- Reduce frequency of [product recalls] [product losses] [associated with biofilms]
- Reduce food recall risk by [reducing] [killing] biofilms
- Synergex just got better now with food contact, no rinse biofilm claims
- Reduce biofilms while you sanitize
- Synergex is designed to kill pathogens on hard, non-porous surfaces, and now those hiding within biofilms
- A solution to your biofilm challenges
- Synergex strengthens your sanitation preventive controls by penetrating biofilms and killing [a minimum of] [6-logs] [99.9999%] of [Pseudomonas aeruginosa] and [Listeria monocytogenes]
- Reduce biofilm loads by [a minimum of] [6 logs] [99.9999%] in food contact [cracks] [and] [crevasses]
- By penetrating the biofilm polysaccharide layer, Synergex can reduce bacteria in biofilms [on hard, non-porous food contact surfaces] [without requiring a rinse] [as a sanitizer]
- [Treat] [kill] [reduce] [sanitize] biofilms within food contact [process] piping before they slough off and cause [food safety] [and] [food] [quality] [risks] [challenges] [concerns]
- Ideal for central sanitize [CIP] systems to [kill] [reduce] [control] the buildup of biofilms
- Are you experiencing periodic quality issues? Synergex can reduce product quality issues caused by biofilms
- No need to "shock treat" your system. Synergex, when used as a biofilm sanitizer, reduces [a minimum of] [6-log] [99.9999%] bacteria [hiding] in biofilms. [No rinse needed]
- [Reduce] [kill] [sanitizes] biofilms [on food contact surfaces] with Synergex.

Read all labels for directions for use, first aid and precautionary statements.

[Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.] [If you cannot read English, ask your supervisor for the appropriate instructions before handling this product.]

[Lea todas las etiquetas para instrucciones de uso, primeros auxilios y medidas preventivas.]

[Note to reviewer: Wording in brackets is considered optional.]

KEEP FROM FREEZING NO DEJE QUE SE CONGELE

DO NOT STORE IN DIRECT SUNLIGHT NO ALMACENE BAJO LA LUZ SOLAR DIRECTA



Antimicrobial Antimicrobiano

#### SECONDARY/USE DILUTION CONTAINER LABEL

(Note to reviewer: This secondary/use dilution container label will be used when the product is diluted up to 2.56 fl. oz. per gallon of water.)

### **Synergex**

(Concentrate Ingredient Statement)

#### **Active Ingredients:**

Hydrogen Peroxide	10.70%
Peroxyoctanoic Acid	
Peroxyacetic Acid	
Other Ingredients:	
Total:	

Diluted product in this container is diluted as directed on the pesticide product label.

Diluted product in this container is fl. oz. per gallon water.

#### **KEEP OUT OF REACH OF CHILDREN**

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

#### FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

Follow the directions for use listed on the concentrate label when applying this product.

Use solution prepared by end user Not for sale or distribution (Do Not Drink)

EPA Reg. No. 1677-250

#### **Emerging Viral Pathogens**

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels" when used in accordance with the appropriate use directions indicated below.

(Note to the reviewer: The statements shall be made only through the following communications outlets: technical literature distributed exclusively to long term care professionals, food safety professionals, environmental services professionals, health care facilities, physicians, nurses, veterinarians and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). *These statements shall not appear on marketed (final print) product labels.*)

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label
Enveloped virus	Reovirus

[Synergex] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [Synergex] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.